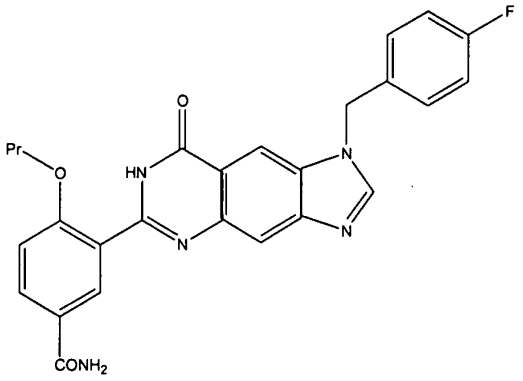


B1

or a pharmaceutically acceptable salt, solvate or polymorph; or a pharmaceutical composition thereof.

In the Abstract

Please delete the Abstract in the specification. Please insert the attached Abstract in the specification.

Remarks

Applicants note the Examiner's remarks regarding the information disclosure statement (IDS) filed in February 2001. An IDS in conformity with 37 CFR 1.98(a)(2), citing the art contained in the aforementioned IDS, will be filed at an early date.

The Examiner's remarks regarding the abstract of the disclosure have been noted. An abstract on a separate sheet of paper is being files as part of the present response.

Reconsideration of the application, as amended, is respectfully requested in view of the following remarks.

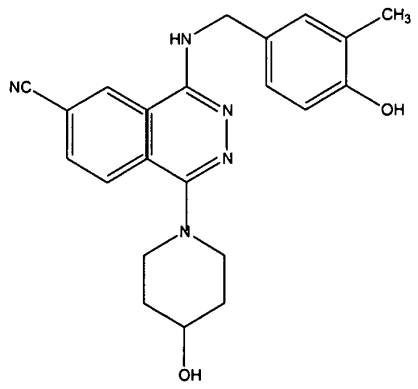
Claims 1-10 are pending in the application. Claim 1 has been amended.

B3

b

Rejection of claims 1-10 under 35 USC § 103 as being unpatentable over Watanabe et al., EP 722,936 A1

Claims 1-10 stand rejected under 35 USC § 103(a) as being unpatentable over Watanabe et al., EP 722,936 A1, (hereinafter "Watanbe"). Claim 1 has been amended to remove the following structure:



The examiner asserts, on page 4 of the office action, that it would have been obvious to a person of ordinary skill in the art at the time the invention was made to select any of the species of the genus taught by the reference, as the ordinary artisan would have the reasonable expectation that any of the species of the genus would have similar properties, and thus, the same use as the genus as a whole.

Applicants submit that claim 1, as amended, is not disclosed or suggested in Watanabe. In particular, Applicants submit that none of the compounds in claim 1, as amended, are encompassed within the genus disclosed by Watanabe. Therefore, it would not have been obvious to the skilled artisan from Watanabe that Applicants' compounds as disclosed in claim 1 would have been effective in the treatment of pulmonary hypertension.

Board of Patent Appeals and Interferences has stated that, "To establish a prima facie case of obviousness, the examiner must present evidence, preferably in the form of some teaching, suggestion, incentive or inference in the applied prior art, or in the form of

generally available knowledge, such that one of ordinary skill in the art would have been led to combine the relevant teachings of the applied references in the proposed manner to arrive at the claimed invention." Ex Parte Levengood, 28 USPQ 2d 1300,1301 (BOPAI,1993).

There is no teaching, suggestion or inference in Watanabe that the PDE5 inhibitor compounds as defined in claim 1 would be effective in the treatment of pulmonary hypertension.

Accordingly, it is submitted that the Examiner has not set forth a prima facie case of obviousness under 35 USC § 103. Reconsideration and withdrawal of the rejection of claims 1-10 in view of Watanabe is respectfully requested.

Rejection of claims 1-10 under 35 USC § 103(a) as being unpatentable over Bell et al., WO 93/07149

Claims 1-10 stand rejected under 35 USC 103(a) as being unpatentable over Bell et al., WO 93/07149, (hereinafter "Bell"). The examiner asserts on page 5 of the office action that Bell et al. discloses a genus that encompasses the compounds defined in Applicants' claims. This assertion is incorrect.

None of the compounds defined in claim 1 of the present invention fall within the generic structure disclosed in Bell. Bell discloses a series of pyrazolo[3,4-d]pyrimidin-4-ones. Sildenafil, for example, is a pyrazolo[4,3-d]pyrimidin-7-one.

Therefore, it would not have been obvious to the skilled artisan from Bell that Applicants' compounds as disclosed in claim 1 would be effective in the treatment of pulmonary hypertension.

As stated above, Board of Patent Appeals and Interferences has state that , "To establish a prima facie case of obviousness, the examiner must present evidence, preferably in the form of some teaching, suggestion, incentive or inference in the applied prior art, or in the form of generally available knowledge, such that one of ordinary skill in the art would have been led to combine the relevant teachings of the applied reference in the proposed manner to arrive at the claimed invention." Ex Parte Levengood, 28 USPQ2d 1300,1301 (BOPAI,1993).

There is no teachings, suggestion or inference in Bell that the PDE5 inhibitor compounds as defined in claim 1 would be effective in the treatment of pulmonary hypertension.

Accordingly, if is submitted that the Examine has not set forth a prima facie case of obviousness under 35 USC § 103. Reconsideration and withdrawal of the rejection of claims 1-10 in view of Bell is respectfully requested.

Attached hereto is a marked-up version of the changes made to the specification and claims by current amendment. The attached page is captioned "Version with markings to Show Changes Made."

In view of the remarks above, it is submitted that the claims in the application are allowable over the prior art of record. Early allowance of the claims is respectfully solicited.

Respectfully submitted,

Date: 7/22/02

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MARKING TO SHOW CHANGES MADE

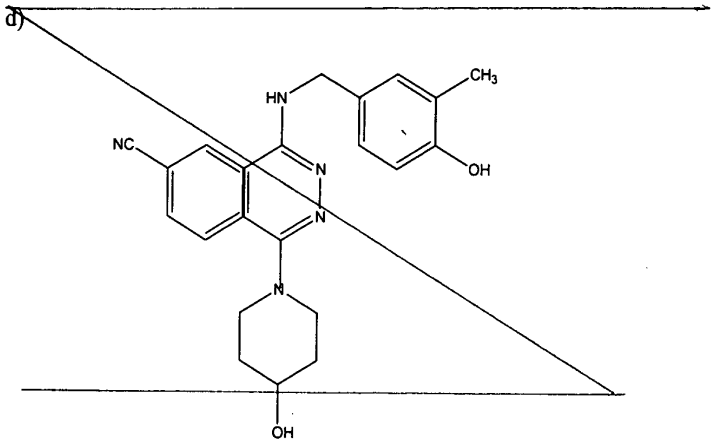
1. A method of treating or preventing pulmonary hypertension in a patient which comprises treating the patient with an effective amount of a PDE5 inhibitor selected from the group consisting of:

a) sildenafil;

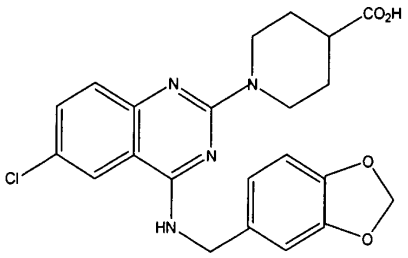
b) (6R, 12aR)-2,3,6,7,12,12a-hexahydro-2-methyl-6-(3,4-methylenedioxyphenyl)-pyrazino[2'1':6,1]pyrido[3,4-b]indole-1,4-dione;

c) 2-[2-ethoxy-5-(4-ethyl-piperazin-1-yl-1-sulphonyl)-phenyl]-5-methyl-7-propyl-3H-imidazo[5,1-f][1,2,4]triazin-4-one;

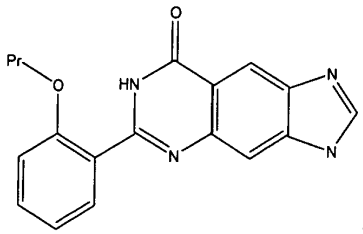
d)



d) ~~e)~~

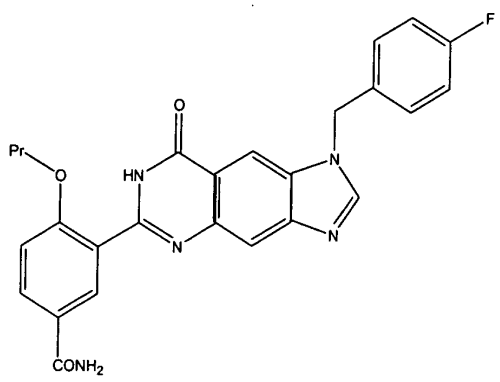


e) ~~d)~~



; and

F) ~~g)~~



or a pharmaceutically acceptable salt, solvate or polymorph; or a pharmaceutical composition thereof.

ABSTRACT

This invention relates to a method of treating pulmonary hypertension by administering certain cyclic guanosine 3',5'-monophosphate phosphodiesterase type five (cGMP PDE5) inhibitors. In one embodiment of the invention, the PDE5 inhibitor is sildenafil.